

## RESTRICTION RESPONSE

The Office has restricted the present application as follows:

Group I – Claims 84-90 and 97-103;

Group II – Claims 91-96

**Applicants elect Group I – Claims 84-90 and 97-103.**

The Office identified the following species for election:

A. a specific contaminating biological agent selected from bacteria, viruses, spores, proteins, peptides and prions; see claims 84, 91, 97 and 102;

B. a specific thermostable kinase selected from adenylate kinase, acetate kinase or pyruvate kinase; see claims 86, 92 and 99;

C. a specific amino acid sequence selected from SEQ ID NO: 1-25 which corresponds to species B; see claims 89, 93 and 100;

D. a specific nucleic acid sequence selected from SEQ ID NO: 26-30 which corresponds to species B and C; see claims 90, 94 and 101.

**Applicants elect, as a single disclosed species, for search purposes only:**

**(A) as the biological agent: Proteins; (B) as the thermostable kinase: Adenylate kinase (*S. acidocaldarius* adenylate kinase); (C) as the amino acid sequence: SEQ ID NO: 2; (D) as the DNA sequence: DNA SEQ ID NOs: 27 (SEQ ID NO: 27 is the *E. coli*-optimized sequence). Claims 84, 85, 97 and 102 are generic to the elected species. All claims of Group I, claims 84-90 and 97-103, read on the elected species.**

The current application is a nationalization stage of a PCT application. A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). 37 CFR 1.475(a).

The present invention discloses a single general inventive concept involving one or more of the same or corresponding special technical features. The present invention discloses the use of a thermostable kinase to validate a treatment process, which may include pH, temperature, an enzyme, a detergent, a chemical sterilant and a gas-phase sterilant, to inactivate a biological infectious agent.

The combination of WO 2004/003226 (the '226 reference), WO 2000/46357 (the '357 reference) and WO 2002/053723 (the '723 reference), does not suggest methods and products of the present invention and, therefore, does not destroy unity of invention. The '226 reference discloses systems "for which temperature is the only rate determining extrinsic factor" ('226 Application, Specification, page 2, lines 24-25), to monitor the thermal impact of thermal processing on an object, by utilizing an enzyme. The enzyme allows a determination of the "thermal history," but does not provide information regarding what effect the "thermal history" has on the object. The '357 reference discloses an assay based on a thermostable kinase, to detect and quantify an analyte, in which high temperature is only used to inactivate endogenous mesophilic kinases. The thermostable kinase is used in the assay to detect the amount of a contaminant in a sample, but it is not used to validate effects of a treatment process on an infectious agent. The '723 reference discloses the use of a thermostable proteolytic enzyme to inactivate TSE infectious agents, in order to reduce the need for "very high temperature and harsh chemical denaturants" ('723 Application, Specification, page 3, lines 23-24). The enzyme is the deactivating agent and maintains its activity. Thus, the enzyme cannot validate effects on the infectious agent and the '723 reference teaches away from the present invention.

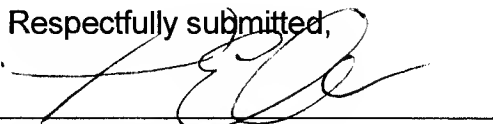
The inventive concept of the present invention relates to the use of a thermostable kinase to validate a treatment process for the inactivation of an infectious agent, by measuring the residual activity of the kinase. None of the citations, either alone or in combination, discloses the use of a thermostable kinase to validate effects on biological infectious agents. Thus, the use of a thermostable kinase to validate the process that results in the reduction of an infectious agent is a special technical feature not shown in any of the cited references. The citations fail to disclose the same methods

and products disclosed by the present inventions. The citations do not destroy unity of invention and, therefore, Groups I and II relate to a single general inventive concept under PCT Rule 13.1. Accordingly, withdrawal of this restriction requirement is respectfully requested.

Applicants submit that the application is now ready for examination on the merits. Early notice of such action is respectfully requested.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Rauch', is written over a horizontal line.

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